REMARKS

Claims 1-27 were pending in the present application. By this Amendment, Applicant has amended claims 1, 4, 15 and 24-27. Applicant has added new claim 28. The present Amendment does not introduce any new matter and, thus, its entry is respectfully requested. Upon entry of the present Amendment, claims 1-27 will be pending and under examination.

The September 26, 2007 Office Action

With regard to the objections to informalities of claim 4 as set forth in page 2 of the outstanding Office Action, the Applicants have amended this claim. Applicants respectfully request that the objections to claim 4 be removed in light of the amendments to claim 4.

With regard to the objections to claims 17, 19, 20, 21 and 23 as set forth in page 2 of the outstanding Office Action, the Examiner appeared willing to remove the objection if the claims are rewritten in independent form to include all of the limitations of the rejected base claim 1. Because each of these claims depends on rejected base claim 1, the Applicants have amended claim 1. For the reasons which follow below, the Applicants respectfully submit that the rejection to base claim 1 should be removed, thereby making it unnecessary to rewrite claims 17, 19, 20, 21 and 23 in independent form. Accordingly, the Applicants believe that the objections to claims 17, 19, 20, 21 and 23 have been rendered moot in light of the amendments to claim 1.

Examiner's rejections under 35 U.S.C. § 101 and § 112, second paragraph.

With regard to the rejections of claims 24-27 under 35 U.S.C. § 101 and 112 for indefiniteness as set forth starting on page 2 of the outstanding Office Action, Applicants point out that these claims are use claims which were filed in Europe because method of treatment claims are not permitted in Europe (the present application arises from PCT/EP04/003238). The use claims in the present application should be interpreted as method claims. Claims 24-27 have been amended to clarify this.

Examiner's rejections under 35 U.S.C. § 112, first paragraph.

With regard to the rejections of claims 24-27 under 35 U.S.C. § 112, first paragraph, as set forth starting on page 4 of the outstanding Office Action, the Examiner is of the opinion that the Specification is not enabling for the full scope of the claims. First, the Examiner asserts that the Applicants have not shown that bone defects can be prevented by use of an osteoinductive protein and a matrix.

While not acquiescing to the propriety of the Office's reasoning, Applicant has obviated the rejection by deleting from claim 25 the recitation "osteoinductive material is used for preventing . . . ."

Second, the Examiner states on page 5, second paragraph of the Office Action that "the claims are directed to administering an *osteoinductive* material comprising osteoinductive proteins and a matrix." (emphasis added.). The Examiner further

contends that there would be undue experimentation to determine how to use a material designed to grow bone in tissues other than bone or the related tissues of cartilage, connective tissue (e.g., tendon, ligament), periodontal tissue, and dental tissue." (emphasis added.). Id. at pp. 5-6.

Applicants respectfully disagree. An applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms. See, e.g., Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) ("While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," the specification must clearly redefine a claim term under this circumstance "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term.") Here, the Applicants have clearly redefined "osteoinductive material" in the Specification as "a biological device comprising at least a matrix material and a morphogenetic protein temporarily immobilized within and/or on the surface of said matrix material." See p. 7, l. 20 of Specification. Because the protein embodiments encompassed by the osteoinductive material of claim 1 are not limited to osteoinductive proteins, the term "'osteoinductive material'" . . . "is not meant to be limited to the use in the area of bone repair." See p. 7, ll. 30-31 of Specification. Thus, the present invention does not encompass the growing of bone in tissues other than bone.

A "morphogenetic protein" is defined in the present application as "a protein of the TGF-β superfamily or a biologically active part or variant thereof." Id. at p. 3, ll. 31-32. These proteins are well known in the art and "[t]he state of the art shows that many members of the TGF-β superfamily of proteins have activity on diverse tissues." See p. 5, 2nd para. of Office Action. Methods of making morphogenetic proteins and administering them in effective amounts to a patient are also well known in the art. See p. 1, ll. 11-15 and p. 4, l. 3 through p. 5, l. 24 of Specification. Therefore, the Applicants respectfully submit that no undue experimentation is necessary for the skilled artisan to practice a method of treating an indication amenable to treatment by administering an osteoinductive material comprising morphogenetic proteins and a matrix.

Examiner's rejections under 35 U.S.C. § 102(b).

With regard to the rejections of claims 1-5, 8, 11-16, 18, 22 and 24-27 under 35 U.S.C. § 102(b) as set forth starting on page 6 of the outstanding Office Action, the Examiner is of the opinion that the present invention is anticipated by EP 0567391A1. Applicants have amended claim 15 so that it is distinguishable from EP 0567391A1 by deleting the limitations of "80 mmol/l or less" and "40 mol/l or less." Applicants have also amended independent claim 1 to make it distinguishable from the cited reference by deleting the acidic pH limitation in "(a)" and including a limitation for a buffer or solvent with a concentration of "20 mmol/l or less" in "(b)."

The claimed product differs from the product of the cited art in that use of the weak ionic concentrations of the buffer or solvent leads to improved evenness and stability of morphogenetic protein coatings. See p. 10, l. 17 to l. 8. Furthermore, use of solvents with ionic concentrations of 20 mmol/l or less enlarges the pH range in which an even and stable coating of matrix materials is possible. See p. 11, ll. 10-32. Thus, the Applicants respectfully request that this rejection be removed.

Examiner's rejections under 35 U.S.C. § 103(a).

With regard to the rejection of claims 6, 7, 9 and 10 under 35 U.S.C. § 103(a) for obviousness as set forth starting on page 8 of the outstanding Office Action, the Examiner is of the opinion that the present invention is anticipated by EP 0567391A1 with EP 1074620A1.

Applicants respectfully submit that the use of buffers or solvents according to limitations (a)-(c) is not rendered obvious by the cited references on the basis of the currently amended claim 1. According to currently amended claim 1, a buffer system or a solution is used capable of maintaining a pH value greater than 9.5, when the ionic concentration is less than or equal to 100 mmol/l, or a pH value greater than 10.3, regardless of ionic strength. Claim 1 also encompasses a buffer or solvent which has an ionic concentration less than or equal to 20 mmol/l, capable of maintaining pH values of less than 5.2.

The EP 0567391A1 reference, on the other hand, teaches away from the present invention. This reference teaches a buffer system with a pH value of 2.5 and a citric acid concentration of 30 mmol/l. The disclosure makes it obvious that a 30 mmol/l citric acid solution mediates the stability of the morphogenetic protein TGF-β1, because a 5 mmol/l HCl solution having a pH value of 2.5 leads to instability of the protein. See col. 7, ll. 36-42 of EP 0567391A1. One of ordinary skill in the art, therefore, would never have considered a stabilization of a morphogenetic protein in an acidic pH region with concentrations less than or equal to 20 mmol/l as in the present invention. Rather, upon knowledge of the EP 0567391A1 reference, the skilled artisan would have been led away from the present invention, because she had to assume that ion concentrations of less than 30 mmol/l in a buffer system with acidic pH values would lead to the destabilization of a morphogenetic protein. Moreover, the EP 0567391A1 reference provides no teaching regarding the stabilization of a morphogenetic protein in alkaline buffers or alkaline solutions. Therefore, the Applicants respectfully submit that the combination of EP 0567391A1 with EP 1074620A1 is improper and that this rejection be removed.

In view of the above amendments and remarks, Applicants believe that all of the Examiner's rejections set forth in the September 26, 2007 Office Action have been fully overcome and that the present claims fully satisfy the patent statutes. Applicants therefore believe that the application is in condition for allowance. The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

January 22, 2008 By / Oscar J. Llorin/

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